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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/689,980	10/13/2000	Nickolai Alexandrov	2750-1237p	3742

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EXAMINER
ZITOMER, STEPHANIE W

ART UNIT	PAPER NUMBER
1634	9

DATE MAILED: 01/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/689,980	ALEXANDROV et al.
Examiner	**Art Unit**
S. Zitomer	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Nov 12, 2002* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above, claim(s) *4 and 25-50* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1a, 2, 3 and 5-24* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election

1. Receipt of applicant's Response to Restriction Requirement filed November 12, 2002 is acknowledged. Applicant has elected Invention I, claims 1a, 2, 3, and 5-24 and SEQ ID NO:1 without traverse.

Possible errors in specification

2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Rejection under 35 U.S.C. 102: Lack of utility

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 1a, 2, 3 and 5-24 are rejected under 35 U.S.C. 101 because the disclosure fails to provide a specific asserted utility nor does the prior art teach a known utility for the claimed invention nucleic acid molecule, SEQ ID NO:1, or any other nucleotide or amino acid sequence of the claimed invention. The claimed nucleotide sequences cannot have specific utility because their functions like those of the corresponding predicted polypeptide sequences are unknown. Table 1 describes SEQ ID NO:1 as a cDNA encoding the predicted polypeptide sequence, SEQ ID NO:2, which is described therein as having a RING finger domain and related to the amino acid sequence AF078825, a RING-H2 finger protein from *Arabidopsis thaliana*. The polypeptide, SEQ ID NO:2, has 100% identity with the *A. thaliana* RING finger protein disclosed by Jensen et al. 1998 (FEBS Lett. 436(2):283-287). A GenEmbl search showed that SEQ ID NO:1 has 99.9% identity with the nucleotide sequence submitted by Jensen et al.. However, neither reference provides a function and/or a utility for the protein or its coding sequence. The specification suggests a number of generic utilities for SEQ ID NO:1 at pages 22-29 that are based on hybridization such as finding similar or identical sequences in other species, genetic mapping including discovering polymorphisms and finding orthologous sequences in related species. Other uses, which

require sequence specificity, such as sense and antisense suppression of expression, ribozymes and chimeraplasts, are described at pages 52-56. Again, however, the description is generic and does not pertain to a specific utility for a specific nucleotide sequence or polypeptide.

Rejection under 35 U.S.C. 112, first paragraph: Nonenablement

> The following is a quotation of the first paragraph of 35 U.S.C. 112:
> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1a, 2, 3 and 5-24 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Rejection under 35 U.S.C. 112, first paragraph: Lack of written description

5. Claims 1a, 2, 3 and 5-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification describes how to make the elected sequence from Table 1 and/or 2, SEQ ID NO:1, by providing its nucleotide sequence and other sequences are similarly described. However, the specification fails to describe how to make a representative number of species of the large genus of claimed nucleic acid molecules of claim 1a comprising a nucleic acid having a nucleotide sequence which encodes an amino acid sequence exhibiting at least 40% sequence identity to an amino acid sequence encoded by SEQ ID NO:1 or any other nucleotide sequence or complements thereof encompassed by the claims. No such representative sequences are identified in the disclosure. The claimed nucleic acid molecule encompasses a large genus of nucleic acid molecules having nucleotide sequences encoding a large genus of amino acid sequences in that, for example, the specification does not indicate whether the percent identity defines a contiguous amino acid sequence of that encoded by the claimed nucleic acid and, if so, where the sequence having 40% identity

begins relative to the encoded amino acid sequence. The specification further fails to describe which encoded amino acids may be replaced or whether conservative or nonconservative changes are permitted. Similarly, the nucleotide sequences of claim 2 and 3 having 65% identity to elected SEQ ID NO:1 or other nucleotide sequence of Table 1 and/or 2 are not described nor does the specification teach how to make this large genus of nucleotide sequence species or complement species. Furthermore, the claimed "fragments" of nucleotide sequences in Table 1 and/or 2 are legion yet no fragments are identified as to size and position relative to the nucleotide sequence. Therefore, the specification not only fails to describe how to make a representative of species encompassed by the claimed nucleic acid molecules of claims 1a, 2 and 3, it also fails to describe a representative number of the large genus of amino acid sequence, nucleotide sequence, fragment and hybridizing species encompassed by the claims. Further in regard to claim 3, the claimed nucleic acid molecule has a nucleotide sequence exhibiting at least 65% sequence identity to a **gene** comprising elected SEQ ID NO:1 or a complement thereof whereas there is no description in the disclosure of any such **gene** or of such a **gene** comprising any other nucleotide sequence of Table 1 and/or 2 or its complement. Genes contain introns and exons, ORFs and regulatory sequences. The specification does not describe even one species of nucleotide sequence having these attributes or those recited in claims 6, 7, 8 and 9. As to claim 5, like claims 1a, 2 and 3, this claim encompasses a large genus of nucleic acid molecules capable of hybridizing to a nucleic acid having a sequence selected from Table 1 and/or 2 or complements thereof wherein the hybridization conditions are recited as permitting duplex formation "at a temperature from about 40°C and 48°C (*sic*) below the melting temperature of the nucleic acid duplex. However, the specification fails to describe any representative species of the large genus of claimed hybridizing nucleic acids or the temperatures at which they form duplexes. Reiterating for claims 6-9, the specification fails to describe an open reading frame (claim 6), a promoter sequence, a 3' end termination sequence, a UTR (claim 7), a TATA or GAAT box, GCAATCG motif or transcription-factor binding sequence or combination thereof (claim 8) or a regulatory sequence having expression-promoting capability for organ-specific sequences as recited in claim 9 for elected SEQ ID NO:1 or any other nucleic acid molecule of the large genus of nucleic acid

molecules encompassed by claim 1. In addition to enablement the first paragraph of 112 requires a "written description". As set forth by the Court in *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, the written description must convey to one of skill in the art "with reasonable clarity" that as of the filing date applicant was in possession of the claimed invention. In the present application, the written description fails to show that applicant was in possession of the large genera of nucleic acid, nucleotide sequence, amino acid sequence and fragment species encompassed by the claims by failing to provide a representative number of species for each claimed genus.

Rejections under 35 U.S.C. 112, second paragraph: Indefiniteness

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1a, 2, 3 and 5-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) The expression "Table 1 and/or 2" renders the claims confusing as to whether some sequences are duplicated in the two tables or some sequences are composed of one or more sequences from each table.

(b) In claims 5 and 7-24 "capable of..." is confusing as to whether a property of a future intended use is recited.

(c) In claims 12, 15, 20 and 23 "first nucleic acid is native to said second nucleic acid" is unclear as to the relationship is heterologous or both nucleic acids are from the same source.

Rejection under 35 U.S.C. 102(b):Anticipation

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1a, 2, 3 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Jensen et al. 1998 (FEBS Lett. 436(2):283-287) with the nucleotide sequence alignment set forth in the GenEmbl database search results, Accession no. AF078825. Applicant has admitted on the record that elected SEQ ID NO:1, which is the same as that of the reference and has the same Accession no., encodes the predicted amino acid sequence (Table 1, page 1). Therefore, the reference sequence meets all of the limitations of claims 1a, 2, 3, and 5.

Conclusion

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephanie Zitomer whose telephone number is (703) 308-3985. The examiner can normally be reached on Monday through Friday from 9:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152. The official fax phone number for this Group is (703) 308-4242. The unofficial fax number is (703) 308-8724. The examiner's Rightfax number is 703-746-3148.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196. For questions and requests relating to formal matters contact LIE Chantae Dessau at 703-605-1237.

S. Zitomer

Stephanie Zitomer, Ph.D.

January 13, 2003

STEPHANIE W. ZITOMER
PRIMARY EXAMINER